IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

Sheila M. Garcia Rivera, *Plaintiff*, v. Balchem Corp., et al., *Defendants.*	Case No. 3:25-cv-1056-CVR

Balchem Corporation's Motion To Dismiss Plaintiff's Complaint
Under Federal Rule of Civil Procedure 12(b)(6)

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Defendant Balchem Corporation ("Balchem") brings this motion to dismiss Sheila M. Garcia Rivera's ("Plaintiff's") Complaint for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

INTRODUCTION

Plaintiff's Complaint should be dismissed for the same reasons as the nearly identical claims in *Perez-Maceira v. Customed*.[1] Balchem is not a medical sterilizer, does not own or operate a sterilization facility in Puerto Rico, and does not emit ethylene oxide ("EtO"). Complaint ¶¶ 19–20, 25, 44, 53, 57, ECF No. 1 ("Compl.").[2] Plaintiff's claims alleging injuries and damages from the alleged emissions of EtO from the medical sterilization facility operated by Steri-Tech, Inc. ("Steri-Tech") simply do not apply to Balchem.

Plaintiff's design defect (**Count V** and **Count VI**) and failure to warn (**Count IV**) claims should be dismissed for the same reasons those product liability claims are not viable in *Perez-Maceira*. Plaintiff does not allege a viable design defect claim because she claims that EtO should no longer be used to sterilize medical products. But EtO cannot be redesigned to omit its only ingredient. Likewise, Plaintiff does not allege a viable failure to warn claim because she does not identify any alleged deficiencies in the warnings Balchem provided to Steri-Tech. Nor does Plaintiff allege that Balchem's failure to warn was the proximate cause of her alleged injuries and damages. Plaintiff's claims for negligence (**Count II**), ultrahazardous activity (**Count III**), battery (**Count VII**), private nuisance (**Count VIII**), trespass (**Count IX**), unjust enrichment (**Count X**), and punitive damages

[1] Plaintiffs' Corrected First Amended Class Action Complaint, No. 3:23-cv-01445 (Feb. 29, 2024), Dkt. 74.

[2] Plaintiff vaguely alleges that "[t]hrough their industrial processes, Defendants worked in concert to emit EtO into the air, allowing it to be carried by the wind and natural air movement throughout the area surrounding the Steri-Tech facility." Compl. ¶ 10. While this allegation may be an attempt by Plaintiff's counsel to plead that Balchem is somehow responsible for emissions from Steri-Tech's facility, Plaintiff does not, and cannot plausibly, allege that Balchem owned or operated Steri-Tech's facility or actually emitted EtO from that facility. Indeed, elsewhere in the Complaint, Plaintiff admits that Balchem is a remote supplier of EtO to Steri-Tech, and Steri-Tech allegedly emits EtO from its own facility. Compl. ¶¶ 19–20, 25, 44, 53.

(**Count XI**) are pleaded against all defendants, but the claims have little or nothing to do with Balchem's alleged conduct. Moreover, most of these claims are simply not viable under Puerto Rico law against a product supplier like Balchem. The battery, unjust enrichment, and punitive damages claims are not properly pleaded against any of the Defendants. Plaintiff's claims are also barred by Puerto Rico's one year statute of limitations for tort claims.

BACKGROUND

I. EtO Is Highly Regulated by Numerous Government Agencies

A. Balchem Distributes an EPA Approved and Labeled Product

The allegations in this and other cases against Balchem are based on the continuing misconception that Balchem "manufactures" EtO. Compl. ¶ 19; Pl's. Ex. 2, Declaration of Emely Hernández ¶ 24, ECF No. 1-2. But the contention remains wholly unsupported because Balchem has never manufactured EtO. Rather, Balchem repackages EtO and supplies it as a sterilant to third parties. *See* Compl. ¶ 44; Pl's. Ex. 1, Bill of Lading, ECF No. 1-1. The EPA-registered product supplied by Balchem is 100% ethylene oxide (CAS NO. 75-21-8).[3] The product is not, as Plaintiff incorrectly describes it, an "EtO-containing product" or an "EtO formula." Compl. ¶¶ 111, 116, 137, 142, 145, 161. The product distributed by Balchem to Steri-Tech is 100% EtO. EtO 100% Label.

The EtO distributed by Balchem is highly regulated by EPA, the Puerto Rico Department of Agriculture, U.S. Food & Drug Administration ("FDA"), and the Occupational Safety and Health Administration ("OSHA"). EtO is registered by Balchem as a pesticide (EPA Reg. No. 36736) and approved for use as a medical sterilant by EPA under the Federal Insecticide, Fungicide, and

[3] *See* Ex. 1, Ethylene Oxide 100%, U.S. EPA: ARC Specialty Products – Balchem Corp., April 8, 2013 (hereinafter "EtO 100% Label"). The Court may take judicial notice of Balchem's product label and ethylene oxide registration. "Courts addressing motions to dismiss product-labeling claims routinely take judicial notice of images of the product packaging." *Sandoval v. PharmaCare US, Inc*., 145 F. Supp. 3d 986, 992 (S.D. Cal. 2015). In assessing a motion to dismiss, a court "may augment these facts and inferences [in the complaint] with data points gleaned from documents incorporated by reference into the complaint, matters of public record, and facts susceptible to judicial notice." *A.G. ex rel Maddox v. Elsevier, Inc*., 732 F.3d 77, 80 (1st Cir. 2013) (citation omitted).

Rodenticide Act ("FIFRA"). Compl. ¶ 46. Balchem also maintains a pesticide registration with the Puerto Rico Department of Agriculture (P.R. Reg. No. 03845-1).

Prior to registration of EtO as a pesticide, EPA required submission of extensive scientific data on EtO, information on its proposed uses, potential toxicity, and labeling. Compl. ¶ 46 n.9.[4] As part of the pesticide registration process, EPA develops risk assessments, including human health risks for all new products ranging "from short-term toxicity to long-term effects such as cancer and reproductive system disorders." *About Pesticide Registration*. EPA also closely regulates all labeling of pesticide products, including EtO:

> We [U.S. EPA] review pesticide product labels as part of the licensing/registration process and must approve all label language before a pesticide can be sold or distributed in the United States. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. It is a violation of federal law to use a pesticide in a manner inconsistent with its labeling. The courts consider a label to be a legal document. In addition, following labeling instructions carefully and precisely is necessary to ensure safe and effective use.

Id. EPA reviewed and approved all language on the EtO 100% label. Compl. ¶¶ 46–47.

As required by law, Balchem's product label is affixed to all EtO distributed in the United States, including Puerto Rico. *See* EtO 100% Label. The label includes numerous warnings regarding human health, cancer, and reproductive dangers. *Id*. The label, which is printed in both English and Spanish, also provides information regarding product hazards and detailed directions for use.[5] In

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[4] U.S. EPA, *How to Register a Pesticide*, https://www.epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process (last updated Feb. 13, 2025) (incorporated by reference in Complaint); *see also* U.S. EPA, *About Pesticide Registration*, https://www.epa.gov/pesticide-registration/about-pesticide-registration (last updated Nov. 6, 2024) ("In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. The company that wants to produce the pesticide must provide data from studies that comply with our testing guidelines."); *Gent v. CUNA Mut. Ins. Soc'y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (judicial notice may be taken of information from an official government website, as such facts are "'not subject to reasonable dispute'") (quoting Federal Rule of Evidence 201(b)).

[5] EtO 100% Label ("It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 29 CFR 1910.1047. This product may be used only in facilities that meet the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047) . . . . This product may be used only by persons who have been trained in accordance with the Ethylene

addition to the label, Balchem's EtO is accompanied by a Safety Data Sheet ("SDS"), which contains an additional list of EtO hazards and information regarding safe handling of the product.[6] Compl. ¶ 44. The SDS provides that airborne levels of EtO must be controlled at facilities: "Emission controls must be in compliance with Federal, State and local regulations." SDS at 7. The SDS includes detailed information on cancer risks from EtO. *Id*. at 10–13. Contrary to Plaintiff's allegation, the SDS has also been translated into Spanish. *See* Compl. ¶ 45; Ex. 2.

B. The Use of EtO by Medical Sterilizers Is Highly Regulated

In addition to significant regulation of EtO as a pesticide, EPA regulates the use and emissions of EtO at sterilization facilities in the United States under the Clean Air Act. EtO emissions are regulated as hazardous air pollutants under Section 112 of the Clean Air Act. 42 U.S.C. § 7412(b)(1). On April 11, 2023, EPA proposed amendments to the Clean Air Act's National Emissions Standards for Hazardous Air Pollutants ("NESHAPs") at commercial EtO sterilization facilities. In announcing the draft Clean Air Act rule for EtO, EPA indicated it had **no plans to ban** the use of EtO and identified the critical importance of EtO for continued use in medical sterilization.[7] On March 14, 2024, EPA announced the final NESHAPs rule.[8]

Oxide Standard (29 CFR 1910.1047). When used to sterilize health care items, this product must be used in non-portable (commercial) ethylene oxide gas sterilizers that have FDA clearance.").

[6] *See* Ex. 2, Ethylene Oxide Safety Data Sheet. New Hampton, NY: ARC Specialty Products c/o Balchem Corp., at 5 (hereinafter "SDS") ("DANGER! Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly Reactive. Harmful or fatal if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.") (incorporated by reference in Complaint).

[7] *See* U.S. EPA, *EPA Proposes to Strengthen Clean Air Act Standards for Ethylene Oxide from Commercial Sterilization Facilities: Fact Sheet*, at 1–2, https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet%20Proposal%20to%20Address%20EtO%20Risks%20from%20Commercial%20Sterilizers.pdf (last visited May 13, 2025) (hereinafter "EPA Fact Sheet").

[8] NESHAPs: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24,090 (April 5, 2024).

EtO use is also highly regulated by the FDA. Compl. ¶ 46 n.8.[9] The FDA closely monitors the use of EtO because of concerns regarding potential shortages of medical devices.[10] The FDA has a "robust standards program" for sterilization of medical devices.[11] Medical sterilizers must obtain FDA approval of their sterilization method prior to entering the sterilization market. Any variance from these standards requires FDA approval. *Id.*

OSHA has strict regulations that apply to all occupational exposures to EtO, including at sterilization facilities. 29 C.F.R. § 1910.1047. OSHA imposes duties on employers including compliance with the occupational safety and health standards under the Act. 29 U.S.C. § 654; *Modern Cont'l Constr. Co. v. OSHA Rev. Comm'n*, 305 F.3d. 43, 49 (1st Cir. 2002) ("[T]he Act places primary responsibility on employers—that is, those who oversee and control the work environment—to achieve compliance with its standards and ensure a safe workplace."). Puerto Rico courts have held that the duties required of employers to employees under OSHA do not extend to manufacturers and suppliers. *See Vulcan Tools of P.R. Inc. v. Makita U.S.A., Inc*., No. 89-148, 1993 WL 719565, at *8 (D.P.R. Sept. 1, 1993), *aff'd*, 23 F.3d 564 (1st Cir. 1994).

OSHA's EtO regulations specify that **employers** are responsible for providing employees with EtO product labels, SDSs, and training. 29 C.F.R. § 1910.1047(j) ("Employers shall ensure that each employee has access to labels on containers of EtO and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(3) of this section."). Under OSHA's

[9] U.S. EPA, *Ethylene Oxide Proposed Interim Registration Review Decision Case Number 2275* (March 2023), at 12–13, https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf (hereinafter "EtO Proposed Interim Registration Review Decision") (incorporated by reference in Complaint).

[10] *See* U.S. FDA, *Ethylene Oxide Sterilization Updates*, (June 2, 2021), https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates ("The FDA is closely monitoring the supply chain effects of closures and potential closures of certain facilities that use ethylene oxide to sterilize medical devices prior to their use. The Agency is concerned about the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care.").

[11] U.S. FDA, *Sterilization for Medical Devices* (Nov. 26, 2024), https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices.

Hazard Communication Standard ("HCS"), employers also are responsible for providing employees with hazardous chemicals information and training. 29 C.F.R. § 1910.1200(b), (h).

C. EtO Is Critical for Sterilization of Medical Devices in the United States

EtO is used to sterilize over 20 billion health care products per year in the United States. Compl. ¶ 38. EtO is used on approximately 50% of all sterilized medical devices, including an estimated 95% of all surgical kits. Compl. ¶ 46 n.8.[12] "EtO is highly valuable in the industrial sterilization setting – or any setting that has the objective of destroying, inactivating, or physically removing all microorganisms to meet defined sterility assurance standards – because it is a penetrative gas that has a high throughput capacity, is effective at a wide range of temperatures, and is compatible with a broad range of materials." *Id.* There are no "viable alternatives" to EtO for certain medical devices.[13] According to EPA and FDA, the "absence of EtO for use on medical devices and equipment would cause widespread disruption to the availability of sterile medical devices including feeding tubes used in neonatal intensive care units, drug-eluting cardiac stents, catheters, shunts, and other implantable devices."[14]

LEGAL STANDARD

The United States Supreme Court has directed that a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). The facts alleged in the complaint "must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544,

[12] EtO Proposed Interim Registration Review Decision at 28 (incorporated by reference in Complaint).
[13] *Id*. ("Presently, there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment because gamma irradiation and e-beam irradiation, the next most commonly employed methods for medical device sterilization, cannot be used on certain materials.").
[14] *Id*. ("Other technologies (e.g., hydrogen peroxide, chlorine dioxide, vaporized peracetic acid) are limited due to issues with material compatibility, scalability, and because they lack accepted validation measures for sterility assurance."); U.S. FDA, Norman E. Sharpless, MD, Acting Commissioner of Food and Drugs, *Statement on concerns with medical device availability due to certain sterilization facility closures* (Oct. 25, 2019), https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures.

555 (2005); *Lozada v. Dejoy*, No. 20-1674, 2023 WL 2433860, at *8 (D.P.R. Mar. 9, 2023) (quotation omitted). A court should grant a motion to dismiss when the complaint provides "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," or the complaint "tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (citations and quotations omitted). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id*. (citation omitted). "A plaintiff is not entitled to 'proceed perforce' by virtue of allegations that merely parrot the elements of the cause of action." *Betancourt-Colon v. Kimco PR Mgmt. Corp*., No. CV 22-1055, 2023 WL 6393065, at *3 (D.P.R. Sept. 30, 2023) (citation omitted). "When allegations, though disguised as factual, are so threadbare that they omit any meaningful factual content, we will treat them as what they are: naked conclusions." *Maddox*, 732 F.3d at 81.[15]

ARGUMENT

I. The Complaint Should Be Dismissed for Failure to State a Claim Against Balchem

A. Plaintiff's Design Defect Claims Should Be Dismissed

Plaintiff's design defect claims (Strict Liability Design Defect (**Count V**) and Negligent Design Defect (**Count VI**)) fail as a matter of law because Plaintiff does not identify a defective design. There is no material difference in how the Court should evaluate Plaintiff's strict liability and negligence claims, both of which are brought under Article 1802 of the Puerto Rico Civil Code of 1930. Plaintiff's claims fail under either theory of design defect.[16]

[15] Certified translations of all cited provisions of the Puerto Rico Civil Code and opinions of the Puerto Rico courts for which official translations were not available, are provided with this motion in compliance with Local Civil Rule 5(c).
[16] Plaintiff's negligent design defect claim (**Count VI**) should be dismissed for the same reasons as the strict liability claim (**Count V**). In addition, Plaintiff fails to plead that Balchem owed a duty specifically to Plaintiff and does not plead that Balchem breached any identifiable standard of care. Compl. ¶¶ 137–41; *Coquí Holdings, CRL v. Maderas 3C, LLC,* No. SJ2021CV01050, 2023 WL 5286421, at *8 (P.R. Ct. App. July 18, 2023).

Article 1802 provides that a person who "by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done." P.R. Laws Ann. tit. 31, § 5141; *Isla Nena Air Servs., Inc. v. Cessna Aircraft Co.*, 449 F.3d 85, 88 (1st Cir. 2006). "A design defect is '[a]n imperfection occurring when the seller or distributor could have reduced or avoided a foreseeable risk of harm by adopting a reasonable alternative design, and when, as a result of not using the alternative, the product or property is not reasonably safe.'" *Garcia v. Hartford Fin. Servs. Grp., Inc*., No. CV 18-2013, 2022 WL 2836272, at *1 (D.P.R. June 1, 2022) (quoting *Defect*, Black's Law Dictionary (11th ed. 2019)). The scope of a design defect claim "does not extend to every conceivable risk, since the manufacturer is not an absolute insurer for all injuries their product may cause." *Coquí Holdings*, 2023 WL 5286421 at *8.

Courts in Puerto Rico have recognized two standard tests for establishing a design defect, including the "consumer-expectancy" test and the "risk-benefit" test. *Garcia*, 2022 WL 2836272 at *1. Under the consumer-expectancy test, the plaintiff must allege that "the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." *Collazo-Santiago v. Toyota Motor Corp*., 149 F.3d 23, 25 (1st Cir. 1998) (citation omitted). Alternatively, under the risk-benefit test, the plaintiff must allege that "the product's design proximately caused his [or her] injury and . . . the benefits of the challenged design outweigh the risk of danger inherent in such design." *Id*. at 25–26 (citation omitted).

The consumer-expectancy test does not apply to Plaintiff's design defect claims because the "test 'cannot be the basis of liability in cases involving complex technical matters.'" *Alvarez-Cabrera v. Toyota Motor Sales, U.S.A., Inc*., No. CV 17-2305, 2020 WL 3620204, at *4 (D.P.R. July 2, 2020) (quoting *Quintana-Ruiz v. Hyundai Motor Corp*., 303 F.3d 62, 77 (1st Cir. 2002)). The consumer-expectancy test is "reserved for cases in which the *everyday experience* of the product's users permit

a conclusion that the product's designs violated *minimum* safety assumptions . . . . The District of Puerto Rico has abstained from using this test in a case involving such a seemingly simple product as an aircraft overhead bin." *Muñiz-Negrón v. Worthington Cylinder Corp*., No. 17-1985, 2021 WL 1199014, at *4 (D.P.R. Mar. 30, 2021) (citation omitted); *see also Fremaint v. Ford Motor Co*., 258 F. Supp. 2d 24, 29 (D.P.R. 2003) (holding that the test is inapplicable in a case "involving complex technical matters" (citation omitted)).

Balchem's EtO is not sold to or used by ordinary consumers, as Plaintiff admits. Compl. ¶ 30 (identifying Defendants as "sophisticated corporations and long-term users" of EtO). EtO can only be used by employees at licensed commercial medical sterilizers. *Id*. ¶¶ 24, 38, 46 n.8;[17] EtO 100% Label. Because the public and ordinary consumers do not use and cannot have expectations regarding EtO's safety and performance as a medical sterilant, the consumer-expectancy test does not apply to Plaintiff's claims. *See Muñiz-Negrón*, 2021 WL 1199014 at *14 (stating that "consumers would likely not have any specific expectations as to how safe propane cylinders should be") (citation and quotations omitted); *In re MBTE Prods. Liab. Litig*., No. M21-88, 2015 WL 3763645, at *4–5 (S.D.N.Y. June 16, 2015) (applying Puerto Rico law) (declining to apply consumer-expectancy test to gasoline additive because courts should only use the "test when a consumer would . . . know what to expect, or . . . how safe the product could be made").

Plaintiff's design defect claims should be dismissed under the risk-benefit test. Under this test, courts consider factors including: "the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the . . . feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design." *Carballo-Rodriguez v. Clark Equip. Co*., 147 F. Supp. 2d

[17] EtO Proposed Interim Registration Review Decision at 12 (incorporated by reference in Complaint).

66, 72 (D.P.R. 2001) (citation omitted). Plaintiff has not pled viable design defect claims under this test.

Instead, Plaintiff alleges that "Defendants' manufacture, distribution, storing, handling and use of the sterilant product as described herein constituted an unreasonably and inherently dangerous design of such products in that **they contained EtO**." Compl. ¶ 124 (emphasis added). **But the product is, in fact, 100% EtO**.[18] The product cannot be redesigned to omit EtO because the product is EtO. "Puerto Rico courts have explained that 'an important part of the risk-utility test is the question of whether there is a safer alternate design which is mechanically feasible.'" *See Muñiz-Negrón*, 2021 WL 1199014 at *5 (quoting *Fremaint*, 258 F. Supp. 2d at 30). There is no feasible way to redesign the EtO 100% sterilant in this case without EtO, as Plaintiff proposes.[19]

Plaintiff also pleads that a variety of alternatives could allegedly be used for medical sterilization instead of EtO, including "mineral oils, silicone fluids, vegetable oils, and nonfluid insulating chemicals," but misses the point. Compl. ¶ 129. Under the applicable legal standard, even if substitutes arguably could be used for EtO sterilization, none of these chemicals is an **alternative design** for EtO. Moreover, Plaintiff's position that EtO is a defective product that can be replaced by other "available" alternatives contradicts the very authorities she cites in her Complaint. Compl. ¶ 46 n.8 (citing EtO Proposed Interim Registration Review Decision at 28, which states "**there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment**" (emphasis added)).[20]

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[18] *See* EtO 100% Label ("Active Ingredient: Ethylene Oxide...100%").

[19] "[S]ome ingredients cannot be eliminated from a design without eliminating the product itself. When the ingredient cannot be designed out of the product, the Restatement (Second) instructs that . . . the proper claim is not design defect." *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co*., 768 N.W.2d 674, 687 (Wis. 2009).

[20] Plaintiff's lengthy description of "market alternatives" including hydrogen peroxide gas plasma, gamma radiation, electron beam (E-Beam) radiation, steam sterilization (autoclaving), vaporized hydrogen peroxide (VHP), peracetic acid, dry heat sterilization, and supercritical carbon dioxide (SCCO2) is likewise irrelevant for purposes of a design defect claim. Compl. ¶ 81. None of these alternatives is an alternative design to EtO. Moreover, none of these alternatives is accepted by EPA and the FDA as a substitute for the sterilization of medical devices in place of EtO. *See supra* note 13.

When a plaintiff attempts to allege a design defect based on the product itself rather than the specific design of the product, courts do not recognize a viable design defect claim. As one court explained, "[t]his is akin to alleging a design defect in champagne by arguing that the manufacturer should have made sparkling cider instead. The challenge is to the product itself, not to its specific design." *City of Phila. v. Lead Indus. Ass'n*, No. CIV. A. 90-7064, 1992 WL 98482, at *3 (E.D. Pa. Apr. 23, 1992), *aff'd sub nom. City of Phila. v. Lead Indus. Ass'n, Inc*., 994 F.2d 112 (3d Cir. 1993). Plaintiff's failure to identify a design defect in EtO requires dismissal of these claims. *See Ayala v. Kia Motor Corp*., 633 F. Supp. 3d 555, 574 (D.P.R. 2022) (dismissing "bald allegations" of design defect where plaintiff did not identify a specific defect).

Plaintiff's speculative suggestion regarding the addition of an odorant to the EtO 100% product (Compl. ¶¶ 43, 130, 141) also is not a proposed redesign of the product; it is a proposal for an entirely new EPA-regulated product containing EtO (the "active ingredient") and an odorant (an "inert ingredient").[21] The amount of EtO cannot be reduced in Balchem's EtO 100% product and still be the **same registered, EPA product**.[22] Instead, this hypothetical new product would require EPA review and approval as a new product. *Id*. The new product would need to undergo toxicity and efficacy testing by EPA and ultimately would have to be marketed and sold as a different product than the 100% EtO product. *Id*.

[21] 40 C.F.R § 152.3 ("*Active ingredient* means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest . . . . *Inert ingredient* means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide . . . .").

[22] Under EPA guidance, alternate formulations are permitted for products, but pesticides cannot have varying amounts of active ingredients. 40 C.F.R. § 152.43 ("(a) A product proposed for registration must have a single, defined composition, except that EPA may approve a basic formulation and one or more alternate formulations for a single product. (b) An alternate formulation must meet the criteria listed in paragraph (b) (1) through (4) of this section . . . . (1) The alternate formulation must have the same certified limits for **each active ingredient** as the basic formulation." (emphasis added)).

FDA also would consider a new EtO product including an odorant a "Novel Sterilization Method"[23] that would require separate FDA review to ensure the safety and effectiveness of the novel product. "[A] sterilization method that uses a combination of chemicals, and the combination has not been previously cleared or approved by FDA as a sterilant, would be considered novel even if the individual chemicals in the combination have been previously cleared or approved independently as chemical sterilants." *Id*. Plaintiff has therefore alleged that Balchem should have supplied Steri-Tech with a completely different product ("EtO with odorant"). But Plaintiff has not identified a design defect in the EtO 100% product that Balchem allegedly manufactured (or supplied) in this case. *See Ayala*, 633 F. Supp. 3d at 574.

Finally, Plaintiff's design defect claims should be dismissed because Plaintiff does not plausibly allege that design defects in EtO could have proximately caused Plaintiff's injuries. *See Muns. of Bayamón v. Exxon Mobil Corp.*, No. 22-1550, 2025 WL 600430, at *41 (D.P.R. Feb. 20, 2025); *see also Ayala*, 633 F. Supp. 3d. at 570 ("Plaintiffs have the burden of proving causation between the design defect and the damage subject of this claim."); *Perez v. Hyundai Motor Co*., 440 F. Supp. 2d 57, 73 (D.P.R. 2006) ("Proximate cause requires that the damages complained of be either a direct result or a reasonably probable consequence of the act or omission at issue."). Plaintiff alleges throughout the Complaint that the cause of Plaintiff's alleged injuries was the emission of EtO from Steri-Tech's facility. Compl. ¶¶ 25, 29, 33, 57, 64–73. Plaintiff therefore cannot plausibly allege that a design defect in EtO proximately caused Plaintiff's alleged injuries. Plaintiff's design defect claims (**Count V** and **Count VI**) should therefore be dismissed with prejudice.

[23] "**A Novel Sterilization Method** is a method that FDA has not reviewed and determined to be adequate to effectively sterilize the device for its intended use." U.S. FDA, *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (Jan. 8, 2024), at 5, https://www.fda.gov/media/74445/download.

B. Plaintiff's Failure to Warn Claim Should Be Dismissed

Plaintiff's failure to warn claim (Failure to Warn or Instruct (**Count IV**)) against Balchem should be dismissed with prejudice. Courts applying Puerto Rico law have held that a plaintiff who alleges a failure to warn claim must plead each of the following: "(1) the manufacturer knew, or should have known of the risk inherent in the product; (2) there were no warnings or instructions, or those provided were inadequate; (3) the absence of warnings made the product inherently dangerous; [and] (4) the absence of adequate warnings or instructions was the proximate cause of plaintiff's injury." *Cruz-Vargas v. R.J. Reynolds Tobacco Co*., 348 F.3d 271, 276 (1st Cir. 2003). To succeed on a failure to warn claim, a plaintiff "must 'adduce evidence that the absence of warnings made the product inherently dangerous.'" *Muñiz-Negrón*, 2021 WL 1199014 at *5 (citation omitted). If a plaintiff's injuries or damages would have occurred regardless of the warning, the plaintiff cannot succeed with the claim. *See Santos-Rodríguez v. Seastar Sols*., 858 F.3d 695, 698–99 (1st Cir. 2017) (upholding dismissal of failure to warn claim where there was no causal connection between alleged failure to warn and plaintiff's alleged injury).

Plaintiff fails to plausibly allege that the warnings Balchem provided to Steri-Tech were inadequate. Compl. ¶¶ 109–18. Balchem distributes EtO with a label and SDS that must comply with EPA and OSHA regulatory requirements. Under FIFRA regulations, Balchem first submitted its EtO label to EPA and obtained EPA's pre-approval prior to distributing EtO on the market. 40 C.F.R. § 156.10(a) ("Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part."); EtO 100% Label. If Balchem sought to amend its label to supplement any of its current warnings, any such label amendments would require EPA approval under federal law. *Id*.[24] And even if this Court ordered Balchem to supplement the label, the label

[24] *See also* U.S. EPA, *Pesticide Registration Manual: Chapter 6 – Amending a Registered Pesticide Product*, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide (last

amendments would have to be reviewed and approved by EPA. Whether EPA would approve any label amendment is ultimately beyond Balchem's or any third party's control.

Contrary to Plaintiff's conclusory allegations that Balchem somehow failed to provide a warning that EtO is potentially dangerous, toxic, and/or carcinogenic (Compl. ¶¶ 109–18), Balchem's EtO label states, in both English and Spanish: "DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD." EtO 100% Label. *See Salvio v. Amgen Inc*., No. 2:11–cv–00553, 2012 WL 517446, at *6 (W.D. Pa. Feb. 15, 2012) (dismissing failure to warn claim because the "warning provided by Defendants advised Decedent's prescribing physicians of the very injury that occurred"); *see also Reed v. Pfizer, Inc*., 839 F. Supp. 2d 571, 576–77 (E.D.N.Y. 2012) (same). The label further instructs that all steps must be taken by those handling EtO to comply with the law and prevent releases of EtO. EtO 100% Label. The label states: "This product may be used only in facilities that meet the requirements of the Ethylene Oxide Standard (29 C.F.R. 1910.1047)." *Id*.

Plaintiff acknowledges that the SDS for EtO includes warnings that EtO is a "[c]ancer and reproductive hazard." Compl. ¶ 44. The SDS for EtO is available in English and Spanish. *See* SDS.[25] The SDS further provides that the medical sterilizers' "[e]mission controls must be in compliance with Federal, State and local regulations." SDS at 7. The SDS provides that all human and airborne exposures to EtO must be avoided and those using EtO must comply with all applicable laws regulating EtO. *See id*. at 7-8; *see Torres*, 896 F. Supp. at 74–75 (holding that manufacturer provided adequate warning where it supplied company with OSHA warnings for chemicals). Finally, Steri-Tech was solely responsible for any communication of warnings related to EtO including product

updated June 5, 2024) ("Almost all modifications to the composition, labeling, or packaging of a registered product must be submitted to EPA with an application for amended registration.").

[25] Contrary to Plaintiff's contentions, Balchem had no legal obligation to provide the SDS to Steri-Tech in Spanish. Compl. ¶ 45; *see Torres-Rios v. LBS Laboratories, Inc*., 152 F.3d 11, 13 (1st Cir. 1998) ("These [OSHA] provisions thus establish that federal law requires manufacturers to provide safety warnings only in English and that it is the responsibility of individual employers, at their discretion, to provide additional warnings in other languages.").

labels, SDSs, and appropriate training to their own employees as required by OSHA. 29 C.F.R. § 1910.1047(j). Because the legally required warnings were provided by Balchem and Plaintiff fails to identify any other warning that could have prevented her alleged injuries, Plaintiff's failure to warn claim against Balchem should be dismissed with prejudice.

Plaintiff also effectively pleads herself out of a failure to warn claim against Balchem on causation grounds because she admits in the Complaint that the end users of the product knew or should have known of the potential dangers of EtO. Compl. ¶ 11 ("At all relevant times, the Defendants knew, or should have known, that EtO is dangerous, toxic, carcinogenic, mutagenic, and causes various illnesses. . . . [I]ts carcinogenic and DNA-damaging effects have been widely studied and known since the 1940s and **definitively known** to Defendants **since at least 1985**. Notwithstanding, Defendants chose to operate their businesses in a way such that EtO is emitted . . ." (emphasis added)). Steri-Tech's alleged knowledge of the dangers of EtO emissions from its facility is a core contention in Plaintiff's Complaint that is repeated over and over again. Compl. ¶¶ 31, 64–66. Plaintiff alleges Steri-Tech was a "sophisticated corporation" with "superior knowledge and access to information regarding the dangers of EtO," but claim "[d]espite knowing these risks" it "did not comply with safe and prudent methods of EtO sterilization." Compl. ¶¶ 30, 32.[26] By Plaintiff's own repeated admissions, the warnings and instructions provided by Balchem regarding EtO through its EtO 100% label and SDS could not have prevented the alleged EtO emissions in this case. Compl. ¶¶ 29, 30-35, 56; *see Santos-Rodríguez*, 858 F.3d at 698–99; *see also Taylor v. Am. Chem. Council*, 576 F.3d 16, 24 (1st Cir. 2009) (holding that "there is no duty to warn an 'end user' of a product's latent characteristics or dangers when the user knows or reasonably should know of those dangers");

[26] *See Torres v. Nat'l Starch & Chem. Corp*., 896 F. Supp. 71, 74–75 (D.P.R. 1995) (holding that a supplier could not be held liable for failure to warn sophisticated buyer of product); *Ordonez v. Norfield Indus*., No. JFM 05-2836, 2006 WL 1892421, at *1 (D. Md. June 1, 2006) (granting motion to dismiss failure to warn claim because plaintiff did not allege that the relevant defendants were not sophisticated users).

SUEZ Water N.Y. Inc. v. E.I du Pont de Nemours & Co., 578 F. Supp. 3d 511, 563 (S.D.N.Y. 2022) (dismissing claim against chemical manufacturer where plaintiff failed to allege warning "would have ameliorated the harm"). By Plaintiff's admission, additional warnings by Balchem would not have prevented Plaintiff's alleged injuries and damages.

Finally, Plaintiff fails to allege, nor could she plausibly allege, that Balchem had a duty to directly warn Plaintiff regarding alleged emissions of EtO from Steri-Tech's facility. Puerto Rico law does not recognize a product supplier's duty to warn the general public about the potential unintended effects of the use of a product by a third party. *See Muns. of Bayamón*, 2025 WL 600430 at *41 (declining to find manufacturers had a duty to warn public about potentially negative effects of the use of petroleum products). Product suppliers generally only have a duty to warn the end users of products. *See Groll v. Shell Oil Co*., 148 Cal. App. 3d 444, 449–50 (Cal. Ct. App. 1983) (holding that manufacturer of lantern fuel was only responsible for providing adequate warnings to distributor); *see also Rodríguez v. Torres*, No. 11-1602, 2015 WL 1138256, at *10, *13 (D.P.R. Mar. 13, 2015) (applying principles in *Groll* under Puerto Rico law); *Walker v. Stauffer Chem. Corp*., 19 Cal. App. 3d 669, 674 (Cal. Ct. App. 1971) (holding that manufacturer had no general duty to warn public about dangers of sulfuric acid). Balchem also could not have feasibly warned unknown third parties regarding EtO emissions from a sterilization facility that it does not own or operate. *See Reichwaldt v. Gen. Motors LLC*, 304 F. Supp. 3d 1312, 1317 (N.D. Ga. 2018) (holding car manufacturer had no duty to warn third parties where duty could not reasonably be fulfilled by manufacturer). Plaintiff does not sufficiently allege that Balchem had a duty to warn Plaintiff, what additional warning Balchem should have provided, nor how such a warning feasibly could have been delivered to the public by a remote product supplier selling a product exclusively used onsite by a sophisticated commercial sterilization facility. Accordingly, Plaintiff's failure to warn claim should be dismissed.

C. Plaintiff's Negligence Claim Should Be Dismissed

Plaintiff has not alleged a viable claim for negligence against Balchem (**Count II**). Plaintiff's negligence claim is based on allegations regarding emissions of EtO from Steri-Tech's facility. Compl. ¶ 91. None of the allegations have anything to do with Balchem's alleged manufacture or actual supply of EtO to the facility.

Plaintiff does not identify the statutory basis for her negligence claim, but Article 1802 of the Civil Code of 1930[27] permits recovery of damages on a showing that a defendant "cause[d] damage to another through fault or negligence." P.R. Laws Ann. tit. 31, § 5141. To plead a negligence claim, "the plaintiff must establish the following: (1) a duty requiring the defendant to conform to a certain standard of conduct; (2) a breach of that duty; (3) proof of damage; and (4) a causal connection between the damage and the tortious conduct." *Sanchez v. Seguros Triple S, Inc*., 687 F. Supp. 2d 6, 9 (D.P.R. 2010).

Plaintiff fails to identify any duty of care Balchem owed to Plaintiff. Nor should the Court create such a duty where none exists as a matter of law. Plaintiff pleads that "Defendants" had a duty of care to Plaintiff in "the safe handling of the EtO, education, training, and supervision of the persons handling the product and the operation of the Steri-Tech facility." Compl. ¶ 92. None of those duties are duties Balchem owed Plaintiff as a product supplier. OSHA's chemical handling, education, training, and supervision requirements place these responsibilities on employers, not product manufacturers or suppliers. 29 C.F.R. § 1910.1200(b), (h); *see Vulcan Tools of P.R. Inc.*, 1993 WL

[27] "Tort liability, both in its extent and nature, is established by the law in force at the time of the act or omission giving rise to such liability." P.R. Laws Ann. tit. 31, § 11720. Moreover, "[i]f any acts or omissions occurred before [the 2020] Code came into force and others occurred after, liability is governed by the previous legislation." *Id.* Since the allegations in this case include facts from before and after 2020, the Puerto Rico Civil Code of 1930 should govern, particularly if any differences arise in the applicable legal standard under the two Codes as to any of Plaintiff's claims.

719565, at *8. Plaintiff does not identify any other legal duty Balchem allegedly owed Plaintiff.[28] Accordingly, Plaintiff's negligence claim against Balchem is not viable.

In addition to failing to plead that Balchem owed a duty to the Plaintiff, Plaintiff fails to plead that Balchem breached any duty to Plaintiff. Plaintiff's allegations relate to operation of the Steri-Tech facility: "Defendants knew or should have known harmful levels of EtO were escaping the Steri-Tech facility and contaminating the community, including Plaintiff's property." Compl. ¶ 91. Plaintiff identifies seven different breaches of duty in the Complaint, but all involve the alleged conduct of Steri-Tech, not Balchem. Compl. ¶ 93; *Jimenez-Ruiz v. Spirit Airlines, Inc*., 794 F. Supp. 2d 344, 351 (D.P.R. 2011) ("As a general rule, an individual is only liable for his own acts or omissions . . . . A third party can only be liable for the acts or omissions of others when clearly specified in the law.") (citations and quotations omitted). As a product supplier, Balchem did not own, operate, or emit EtO from the Steri-Tech facility. *See* Compl. ¶¶ 19-20, 44, 53. Notably, Plaintiff does not, and cannot, allege that Balchem had control over or engaged in any activities relating to the operation of Balchem's sterilization equipment or air pollution controls or had access to Steri-Tech's internal emissions, monitoring, testing, or reporting data. Compl. ¶ 93. All such activities were the sole responsibility of Steri-Tech. Compl. ¶¶ 25, 29, 32-33, 57. Accordingly, Plaintiff fails to plead a negligence claim against Balchem. *See López-Rivera v. Hosp. Auxilio Mutuo, Inc*., 247 F. Supp. 3d 185, 189 (D.P.R. 2017) ("Even under the rules of 'notice pleading,' the plaintiff must 'satisfy the requirement of providing . . . [the] grounds on which the claim rests.'" (citation omitted)). Finally, Plaintiff's failure to plead that Balchem was the proximate cause of Plaintiff's injuries provides further grounds for dismissal of this claim. Compl. ¶¶ 25, 29, 32-33, 94-95.

[28] To the extent Plaintiff realleges that Balchem had a duty to warn Plaintiff (Compl. ¶ 93(c)), no court in Puerto Rico has imposed such a duty on a product manufacturer. *See Muns. of Bayamón*, 2025 WL 600430 at *41.

D. Plaintiff's Private Nuisance Claim Should Be Dismissed

The Court should dismiss Plaintiff's private nuisance claim (**Count VIII**) against Balchem with prejudice because it is based on alleged emissions of EtO. Compl. ¶¶ 154–58. Puerto Rico law generally defines "nuisance" as "anything which is injurious to health, indecent, or offensive to the senses, or an obstruction to free use of property so as to interfere with the comfortable enjoyment of life or property, or that is a nuisance to the well-being of a neighborhood, or to a large number of persons . . . ." Art. 277 of the Code of Civil Procedure, P.R. Laws Ann. tit. 32, § 2761. To obtain relief based on a nuisance theory, a plaintiff must show that the defendant's activities and conduct "exceed[ed] the bounds of reasonableness" and imposed an excessive burden on the plaintiff. *Casiano v. Lozada Torres*, 91 P.R. Dec. 488, 493, 91 P.R. 473, 478 (1964). Even if an activity is declared a nuisance, Puerto Rico courts have held that the availability of damages under Article 277 depends on the plaintiff establishing the elements of a traditional tort, including actual damages and causation. *See Martínez Romero v. Super Asphalt Pavement, Co*., No. KLAN201701052, 2018 WL 3037397, at *10–11 (P.R. Ct. App. Apr. 23, 2018).

Plaintiff cannot plausibly allege a claim for private nuisance against Balchem because Plaintiff does not allege that Balchem owned or operated Steri-Tech's facility in Puerto Rico. Compl. ¶¶ 19-20, 25, 44, 53, 57. Balchem therefore could not have caused the alleged emissions of EtO that Plaintiff claims caused her injuries and damages. *See Muns. of Bayamón*, 2025 WL 600430 at *42 (recommending dismissal of climate change nuisance claims on causation grounds where defendants did not operate facilities or burn fossil fuels in Puerto Rico); *see also Scarlett & Assocs., Inc. v. Briarcliff Ctr. Partners, LLC*, No. 1:05-cv-0145, 2009 WL 3151089, at *15 (N.D. Ga. Sept. 30, 2009) ("The essential element of nuisance is control over the cause of the harm."). Plaintiff's nuisance claim against Balchem should therefore be dismissed with prejudice.

E. Plaintiff's Ultrahazardous Activity Claim Should Be Dismissed

Plaintiff's ultrahazardous activity claim (Strict Liability Ultrahazardous Activity (**Count III**)) is not viable as a matter of law. First, the ultrahazardous liability claim fails because Plaintiff alleges injuries and damages that pre-date the Civil Code of 2020. P.R. Laws Ann. tit. 31, § 11720. No claim for "ultrahazardous activity" applies under the applicable Civil Code of 1930. Second, even if such a claim existed under the Civil Code of 1930, Plaintiff has failed to plead that Balchem was engaged in an ultrahazardous activity in Puerto Rico. Plaintiff alleges that "the use and emission" from Steri-Tech's facility "constitutes a highly hazardous or ultrahazardous activity." Compl. ¶ 99. Again, Plaintiff cannot reasonably dispute that Balchem did not own or operate Steri-Tech's facility. Compl. ¶¶ 19–20, 25, 44, 53, 57. Accordingly, the ultrahazardous liability claim against Balchem must be dismissed with prejudice.

F. Plaintiff's Battery Claim Should Be Dismissed

Plaintiff's battery claim (**Count VII**) should be dismissed with prejudice. Puerto Rico applies common law principles with respect to battery claims. *See Escalera-Salgado v. United States*, 261 F. Supp. 3d 163, 168-69 (D.P.R. 2016). Under common law principles, a battery claim requires plaintiff to plead three elements: (1) defendant intended to cause a "harmful or offensive contact with [a] person"; (2) "an imminent apprehension of such a contact"; and (3) harmful contact with the person. *Id.* at 169. Plaintiff's far-fetched battery claim fails for multiple reasons. First, Plaintiff does not allege that Balchem actually emitted the EtO that allegedly came into contact with her or her property. Compl. ¶¶ 19–20, 25, 53, 57. Second, Plaintiff does not allege, nor could she allege, that Balchem intended for EtO to come into contact with her. *See Shaw v. Brown & Williamson Tobacco Corp.*, 973 F. Supp. 539, 548 (D. Md. 1997) (dismissing battery claim where cigarette manufacturer did not manufacture, market, or distribute cigarettes with the purpose of "touching non-smokers with second-hand smoke" or "know with a substantial degree of certainty that second-hand smoke would touch

any particular non-smoker"); *Acosta Orellana v. CropLife Int'l*, 711 F. Supp. 2d 81, 91 (D.D.C. 2010) (dismissing battery claim against pesticide trade association where plaintiffs failed to plead association intended to commit contact with pesticide). Accordingly, Plaintiff's battery claim should be dismissed with prejudice.

G. Plaintiff's Trespass Claim Should Be Dismissed

Plaintiff's trespass claim (**Count IX**) should be dismissed with prejudice. Article 475 of the Civil Code of 1930 states that, "[e]very possessor has a right to be respected in his possession; and if he is disturbed therein, he shall be protected or reinstated in such possession by the means established in the laws of procedure." P.R. Laws Ann. tit. 31, § 1461.[29] Although Puerto Rico recognizes trespass claims, such claims are not viable against a remote product supplier like Balchem. Federal courts have routinely held that the mere supply of a product to a third party is not sufficient to cause a trespass. *See City of Bloomington, Ind. v. Westinghouse Elec. Corp.*, 891 F.2d 611, 615 (7th Cir. 1989) ("In accordance with the Restatement principles, courts do not impose trespass liability on sellers for injuries caused by their product after it has left the ownership and possession of the sellers.").[30] Plaintiff alleges that her injuries occurred after the EtO left Balchem's possession and control. Compl. ¶¶ 19-20, 25, 33, 44, 53. There are no allegations in the Complaint, nor could there be, that Balchem actually emitted EtO from Steri-Tech's facility. Accordingly, Plaintiff's trespass claim against Balchem should be dismissed with prejudice.

[29] This article has been interpreted to address trespass to real property. *Veve v. Corporan*, 977 F. Supp. 2d 93, 105-06 (D.P.R. 2013) ("[A] person who enters upon lands of another without the consent and to the damage of its owner commits trespass, and it has been said that 'a person who enters upon the land of another without leave to lead off his own runaway horse and who breaks a blade of grass in so doing commits a trespass.'" (quoting *García v. Rodríguez*, 27 P.R.R. 284, 27 D.P.R. 305 (1919)).

[30] *See also Town of Westport v. Monsanto Co.* No. 14-12041, 2015 WL 1321466, at *5 (D. Mass. Mar. 24, 2015); *Jordan v. S. Wood Piedmont Co.*, 805 F. Supp. 1575, 1582–83 (S.D. Ga. 1992); *Town of Hookset Sch. Dist. v. W.R. Grace & Co.*, 617 F. Supp. 126, 133 (D.N.H. 1984).

H. Plaintiff's Restitution Claim Should Be Dismissed

Plaintiff's restitution claim (**Count X**) should be dismissed with prejudice. There are five elements required to state a restitution or unjust enrichment claim under Puerto Rico law: (1) existence of an enrichment; (2) a correlative loss (impoverishment); (3) nexus between the loss and the enrichment; (4) lack of cause to justify the enrichment; and (5) absence of a legal precept excluding application of the enrichment without cause doctrine. *See Ortiz Andújar v. Commonwealth*, 22 P.R. Offic. Trans. 774, 780, 122 P.R. Dec. 817, 823 (1988).

First, Plaintiff fails to plead the five elements required to state a claim for unjust enrichment. Compl. ¶¶ 166–69. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *López-Rivera*, 247 F. Supp. 3d at 187 (citation omitted). Second, Plaintiff's decision to plead other tort claims precludes her from pleading an unjust enrichment claim. An unjust enrichment claim is not available in Puerto Rico when another cause of action under the general tort statute is also pleaded. *See Muns. of Bayamón*, 2025 WL 600430 at *42 (recommending dismissal of unjust enrichment claim where other relief was available); *see also Ocaso, S.A., Compañía De Seguros y Reaseguros v. P.R. Mar. Shipping Auth*., 915 F. Supp. 1244, 1263 & n.15 (D.P.R. 1996) (dismissing unjust enrichment claim where "[d]efendants' allegedly fraudulent conduct would allow for a claim sounding in tort under art. 1802 of the P.R. Civil Code," despite time-bar on tort action).

I. Plaintiff's Claims Are Time-Barred

Plaintiff's claims are time-barred because her alleged injuries occurred more than a year prior to initiation of her lawsuit. Plaintiff alleges she has lived near Steri-Tech's facility for forty years, and she alleges that was diagnosed with breast cancer in 2019. Compl. ¶¶ 69-70.[31] Because Plaintiff's

[31] At the latest, Plaintiff had knowledge of her injury when she was diagnosed. *See, e.g.*, *Kwasnik v. 160 Water St., Inc.*, No. 06 CIV. 1520, 2014 WL 7181171, at *1 (S.D.N.Y. Sept. 30, 2014) ("Discovery of the injury refers to 'the discovery

claims sound in tort, Puerto Rico's one-year statute of limitations "for general tort claims" bars her claims. *Torres v. Hosp. San Cristobal*, 831 F. Supp. 2d 540, 543–44 (D.P.R. 2011); P.R. Laws Ann. tit. 31, § 5298. "[W]hen a tort claim is filed more than one year after the injury was caused, the plaintiff bears the burden of proving the timeliness of his claim as well as the lack of knowledge to assert it within the statutory period." *Torres*, 831 F. Supp. 2d at 544.

Plaintiff does not explain why her claims were filed late. In August 2022 and January 2023, EPA hosted public meetings about EtO for the Salinas community in which Plaintiff alleges she has lived for forty years.[32] Other plaintiffs living in the same community filed suit in the *Perez-Maceira* case in August 2023 approximately one year after EPA's first public meeting.[33] "[A] plaintiff will be deemed to have 'knowledge' of the injury, for purposes of the statute of limitations, when she [he] has 'notice of the injury, plus notice of the person who caused it.'" *Bado-Santana v. Ford Motor Co.*, 283 F. Supp. 2d 520, 527 (D.P.R. 2003) (citation omitted). "[T]he plaintiff need not 'know the exact name of the tortfeasor' to satisfy the requirement of knowledge of the person who caused the injury." *Kaiser v. Armstrong World Indus., Inc.*, 678 F. Supp. 29, 31 (D.P.R. 1987) (citation omitted), *aff'd*, 872 F.2d 512 (1st Cir. 1989).

Even if Plaintiff was not put on notice by EPA's public meeting, where, as here, Plaintiff pleads that the injury occurred years ago, she must—at a minimum—"plead *some* facts 'sufficient to give notice of [her] reliance on the discovery rule.'" *Quality Cleaning Prods. R.C., Inc. v. SCA Tissue N. Am., LLC*, 794 F.3d 200, 207 n.4 (1st Cir. 2015) (citation omitted). "The discovery rule is not a tool that plaintiffs may employ at-will to evade the statute of limitations. . . . its tolling benefit ends

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of the manifestations or symptoms of the latent disease that the harmful substance produced.' . . . The plaintiff's injury need not be medically diagnosed for the statute to begin running." (citation omitted)).

[32] U.S. EPA, *Salinas, Puerto Rico (Steri-Tech, Inc.)*, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/salinas-puerto-rico-steri-tech-inc (last visited May 13, 2025).

[33] *Perez-Maceira v. Customed*, No. 3:23-cv-01445 (D.P.R. Aug. 29, 2023).

once a plaintiff discovers her injury. Therefore, a plaintiff cannot plausibly suggest that the discovery rule applies to her claim unless she **alleges the date on which she learned of her injury**." *In re Processed Egg Prods. Antitrust Litig.*, 931 F. Supp. 2d 654, 658 (E.D. Pa. 2013) (emphasis added); *see also Griggs v. Robinson Secs.*, No. 84 C 4679, 1985 WL 1163, at *5 (N.D. Ill. May 9, 1985) ("[I]t is the plaintiff's duty to affirmatively and particularly plead the date of discovery or face dismissal."). Likewise, if Plaintiff alleges that she has been injured by a continuing tort, she must identify her continuing injury. *See Torres*, 831 F. Supp. 2d at 544. She cannot merely allege a continuing harmful effect from her injury. *Id.*; Compl. ¶ 71-72. Accordingly, Plaintiff's claims should be dismissed for failure to file within Puerto Rico's strict one-year deadline for tort claims.

J. Plaintiff's Punitive Damages Claim Should Be Dismissed

Plaintiff's punitive damages claim (**Count XI**) is not viable. Because Plaintiff's claims are brought under the Puerto Rico Civil Code of 1930, punitive damages are not available. *Díaz-Morales v. Universidad de P.R.*, No. 20-1630, 2023 WL 3177792, at *2 (D.P.R. May 1, 2023) (dismissing claim for punitive damages because "relevant events occurred in 2019" and "punitive damages were **prohibited** under the Puerto Rico Civil Code of 1930"); *Ramírez de Arellano v. E. Air Lines, Inc.*, 629 F. Supp. 189, 192 (D.P.R. 1985) (holding that Puerto Rico Civil Code of 1930 does not allow punitive damages claims). Accordingly, Plaintiff's punitive damages claim should be dismissed with prejudice.

CONCLUSION

For the reasons set forth above, Balchem respectfully requests dismissal of the Complaint with prejudice.

Dated: May 14, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify, that on May 14, 2025, this document was filed with the Court's CM/ECF system, which will simultaneously serve notice on all counsel of record to their registered email addresses.

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